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IN THE

Supreme Court of the United States

October Term 1948
No. 274

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET, an individual,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

Petition for a Writ of Certiorari to the United States Court of Appeals for the Ninth Circuit and Brief in Support Thereof.

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SUBJECT INDEX

TABLE OF AUTHORITIES CITED

STATUTES PAGE

TEXTBOOKS

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Petition for a Writ of Certiorari to the United States Circuit Court of Appeals for the Ninth Circuit.

To the Honorable Fred M. Vinson, Chief Justice, and to the Associate Justices, of the Supreme Court of the United States:

Petitioners, Pasadena Research Laboratories, Inc., and Russell R. Bavouset, respectfully pray the grant of a Writ of Certiorari to review a judgment of the United States Circuit Court of Appeals for the Ninth Circuit entered on July 16, 1948, in the above-entitled action. The transcript of record in one volume is supplied.

Summary and Short Statement of Matter Involved.

On March 18, 1947, an Information [R. 2] was filed in the District Court for the Southern District of California, Central Division, naming as defendants Pasadena Research Laboratories, Inc., a corporation, and Russell R. Bavouset, an individual, both of whom are petitioners[1] herein, and alleging the violations of the Federal Food, Drug and Cosmetic Act, 21 U. S. C. A. 331 and 333 in that they "did * * * unlawfully cause to be introduced and delivered for introduction into interstate commerce" drugs[2] which were then and there adulterated and misbranded. Both petitioners were found guilty on counts I to IV and VII, and not guilty on counts V and VI, the corporation being fined $3,000.00 and the individual being placed on five years' probation [R. 20 and 21].

The evidence, much of which was established by stipulation, showed that the drugs involved were introduced into interstate commerce by petitioners and shipped to doctors' offices, where Government inspectors picked them up and forwarded them to the Food and Drug Administration, Washington, D. C. [R. 14 to 16]. Thereafter the drugs were tested by the Government expert witnesses who testified at the trial.

At the trial the Government's expert witnesses (one of whom testified with regard to each drug involved)

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[1]The petitioners herein were the appellants in the Circuit Court of Appeals.

[2]Three separate drugs are involved. Counts I and II [R. 2 and 4] allege adulteration and misbranding of Indoform [Exs. 3 and 4]; Counts III and IV [R. 5 and 7] allege adulteration and misbranding of Pluri-B [Exs. 6 and 7]; and Count VII [R. 10] alleges adulteration because of the presence of undissolved material in Pluri-B [Exs. 1 and 2].

testified that the tests showed that the drugs when tested were adulterated and misbranded.[3]

Each expert witness then, in answer to a hypothetical question, stated in his opinion that the drugs were adulterated and misbranded at the time they were introduced into interstate commerce.[4]

The hypothetical questions propounded to the witnesses Mason and Capps asked the witnesses to *assume* that the drugs were handled in "a normal and careful manner" [R. 75] or "received ordinary and reasonable care and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather" [R. 100, 101]; and the hypothetical question propounded to Wiley asked him to base his answer on his knowledge of sterile solutions, observation of sterile solutions and experience [R. 41, 42], and did not even ask him to consider what care or handling the drug may have been subjected to after it had been introduced into interstate commerce by petitioners.

The Government, the respondent herein, introduced no evidence whatsoever to support the assumptions contained

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[3]The witness Mason testified that at the time he made his test of contents of the vial, Ex. 3, it contained practically no posterior pituitary [R. 59]; the witness Capps testified that at the time he examined the contents of Ex. 6 it contained 33 milligrams of thiamine hydrochloride (vitamin B-1) instead of 50 milligrams, as stated on the label, Ex. 7 [R. 100]; and the witness Wiley testified that at the time he inspected Ex. 1 they were badly contaminated with undissolved material [R. 34].

[4]A crime was committed only if the drugs were "* * * when caused to be introduced and delivered into interstate commerce * * * then and there adulterated within the meaning of Section 21 U. S. C. A. 351(c) * * *," or "* * * then and there misbranded within the meaning of 21 U. S. C. A. 352(a) * * *." Counts I, III, and VII charge adulteration, while Counts II and IV charge misbranding.

in the hypothetical questions and required to be made by the expert witnesses in giving their opinion; and introduced no evidence whatsoever showing how the drugs had been cared for or handled, or the temperatures or conditions to which they had been subjected after being introduced into interstate commerce by petitioners, or showing that the drugs did not become adulterated at some later time after they had been shipped by petitioners.

Petitioners introduced affirmative evidence establishing that the vials of Exhibit 1 (Count VII) at the time they were shipped were carefully inspected and contained no precipitate or undissolved material.[5] Also with regard to the bottles, Exhibits 3 and 6 (Counts I and III), Bavouset testified he made the solutions and that they had the full strength and potencies as set forth on the labels [R. 110, 114, 115].

Petitioners also introduced evidence to show that the drugs involved are unstable in character and will change in potency and precipitates may form in them if not kept under proper conditions of temperature and light, and if not properly handled [R. 185, 115, 149, 145, 150]; if they become contaminated by sterilizing agents used by doctors to sterilize hypodermic needles [R. 161, 163]; if

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[5]Bavouset testified control batches are kept for a short time after the material has been shipped; that a very careful inspection is made the last thing before the drugs are placed in shipping cartons and sent out and marketed; and that at the time of shipment there was no precipitate in the bottles [R. 118, 119].

Mrs. Smiley testified she was in charge of the Shipping Department, that she examined the solutions in the vials of Ex. 1 to be sure there were no particles in them, and she positively remembers there were no particles in these vials when she examined them for that purpose by means of an inspection lamp, that she remembered this particular shipment because it was unusual to have an order as large as 50 bottles [R. 120 to 122].

air containing oxygen gets into the material [R. 163]; or if doctors add other materials to the drugs [R. 171 and 172]. The Government expert witness Wiley admitted that temperatures slightly above freezing would hasten or increase precipitation [R. 42]. In addition, the Government stipulated that doctors "deliberately insert other things into bottles to make a different combination of a product" [R. 168].

The Court below rejected petitioners' contention that it was incumbent on the Government to introduce at least some evidence of proper handling and care after petitioners had introduced the drugs into interstate commerce and held: first, that there is a presumption of proper performance and regularity of official acts of public officers [Court's Opinion, R. 247]; and, second, that there is a presumption that the acts of private individuals are rightfully done, quoting from the civil case of *United States Bank v. Dandridge,* 25 U. S. 64 [Court's Opinion, R. 248].

Based on these holdings the Court below filled in the *hiatus* in the Government's proof by invoking the presumption of official regularity as to the Government chemists and as to the proper handling and absence of tampering on the part of postal employees through whose hands the shipments had passed [Court's Opinion, R. 248].

The Court went further and invoked the presumption of regularity of the acts of private individuals as follows:

> "This presumption that even private individuals do their duty and exercise due care should apply a fortiori to doctors and nurses, whose professional

training and traditions teach them to be meticulous in the handling of preparations that are to be administered to their patients." [Court's Opinion, R. 249.]

The Court below further supported its position by stating that petitioners "had not pointed out, nor have we been able to find, a single scintilla of evidence in the record" [Court's Opinion, R. 250] to indicate mishandling by anyone. Thus indicating that the Court below considered that petitioners had the burden of establishing their innocence by the introduction of affirmative evidence.

Jurisdiction.

The judgment of the Circuit Court of Appeals was entered on July 16, 1948 [R. 259]. On August 10, 1948, petitioners obtained from this Court an extension of time to September 14, 1948, within which to file this petition. The Information was filed under the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. A. 321). The jurisdiction of this Court is invoked under Section 240(a) of the judicial Code as amended by the Act of February 13, 1925 (28 U. S. C. A. 347).

The Questions Presented.

1. In a criminal case based on an alleged violation of the Federal Food, Drug and Cosmetic Act where the drugs are unstable and liable to change if not properly handled and cared for, can the accused be convicted of a crime of *introducing* adulterated and misbranded drugs into interstate commerce where there is no evidence to prove that the drugs when tested by the Government expert witnesses were in the same condition as when the drugs were *introduced* into interstate commerce by the accused, and

no evidence showing how the drugs were cared for or handled, or the conditions to which the drugs were subjected between the time they were *introduced* into interstate commerce by the accused and picked up by the Government inspectors?

2. In a criminal case based on an alleged violation of the Federal Food, Drug and Cosmetic Act where the drugs are unstable and liable to change if not properly handled and cared for, does the presumption of innocence prevail as against a presumption that the acts of private individuals are rightfully done; namely that the doctors and nurses properly handled and cared for the drugs?

3. In a criminal case based on an alleged violation of the Federal Food, Drug and Cosmetic Act where the drugs are unstable and liable to change if not properly handled and cared for, where the accused introduced evidence showing that the drugs when *shipped* by them were not adulterated or misbranded, can the accused be convicted of adulteration and misbranding where to support such conviction the court must indulge in a presumption that the drugs were properly handled and cared for after *shipment* by the accused?

4. In a criminal case based on an alleged violation of the Federal Food, Drug and Cosmetic Act where the drugs are unstable and liable to change if not properly handled and cared for, is it incumbent on the accused to establish his innocence by affirmatively proving that the drugs became adulterated after the accused *introduced* them into interstate commerce?

5. In a criminal prosecution based on a charge of violating the Federal Food, Drug and Cosmetic Act, should the Act be strictly construed?

The Reasons Relied on for the Allowance of the Writ.

1. The decision of the Circuit Court of Appeals has decided an important question under the Federal Food, Drug and Cosmetic Act which has not been, but should be, settled by this Court.

The question of whether in a criminal case under the Federal Food, Drug and Cosmetic Act, involving drugs which are unstable and liable to deteriorate, the Government must prove proper handling and care of the drugs after they have been introduced into interstate commerce by the accused, or whether the accused must introduce evidence showing mishandling and improper care of the drugs after they have been introduced into interstate commerce by the accused is of great importance to all persons involved in Federal Food, Drug and Cosmetic Act criminal cases, including not only the defendants but the Government as well. At the present time there is no ruling by this Court to guide the Government or the defendants in the prosecution and defense of cases of this type. This question can and undoubtedly does arrive in a majority of the criminal cases under the Federal Food, Drug and Cosmetic Act. For example, in the case of *United States v. Boyle and Boyle,* No. 18,940 Criminal, in the District Court of the United States in and for the Southern District of California, Central Division, Judge Cavanah, in an unreported decision, certified copy of which is appended hereto as Appendix A found the defendants not guilty because "there was an opportunity which existed from the time the defendants are charged with shipping this product into interstate commerce—which is the time when the crime has to be committed—and the time it went through these different cities, to Washing-

ton, where the analysis was made by the Government, and upon which the government predicates its direct proof of guilt, for conditions to be present which might have caused a change in the potency of the product as represented at the time it was shipped." [Appendix A, p. 44.]

This holding is directly contrary to the holding of Judge Mathes, Trial Judge in the present case, and the holding of the Circuit Court of Appeals. With this question settled by this Court all parties in the future will know definitely what their obligations are as to this matter of proof.

2. The Circuit Court of Appeals has decided important questions which are in conflict to the decisions of other Circuit Courts of Appeals, District Courts, State Courts, and are in conflict with well established principles of criminal law evidence.

The Court below in holding in effect that it is unnecessary to introduce any evidence whatsoever of proper handling and care of drugs which are unstable and likely to deteriorate after they have been introduced into interstate commerce is in conflict with *United States v. S. B. Penick & Co., et al.*, 136 F. (2d) 413, wherein the Circuit Court of Appeals for the Second Circuit held that before a physical object connected with the commission of a crime can be properly admitted in evidence "there must be a showing that such object is in substantially the same condition as when the crime was committed. 2 Wharton, Criminal Evid., 11th Ed. §757." After stating that there is no hard and fast rule that the prosecution must exclude *all possibility* that the article may have been tampered with, and held:

> "* * * In each case the trial judge before he admits it in evidence must be satisfied that in reason-

able probability the article has not been changed in important respects. Wigmore, Evidence, 3d Ed., §437(1); 32 C. J. S., Evidence, §607. In reaching his conclusion *he must be guided by* the nature of the article, *the circumstances surrounding the preservation and custody of it*, and the likelihood of intermeddlers tampering with it. * * *" (Italics added.) (p. 415.)

In *United States v. Buffalo Pharmacal Co.*, 131 F. (2d) 500, the Circuit Court of Appeals upheld the conviction of one of the defendants because there was some evidence to indicate that the bottle of digitalis in question had been properly cared for. The Court said:

"* * * While cross-examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, there was some testimony to indicate that the bottle in question had been properly cared for. We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding." (p. 502.)

In *Novak v. District of Columbia*, 49 A. (2d) 88, the Court held that it was incumbent upon the Government to prove that the specimen taken from defendant and the one analyzed by the chemist and reported on in court were the same, and in substantially the same condition when tested as when taken, the Court said:

"* * * We agree that it was still incumbent upon the government to prove that the specimen taken from defendant and the one analyzed by the chemists, and reported on in court, were the same and were in substantially the same condition when tested as when taken. * * *" (p. 90.)

The holding of the Court below in this case that there is a presumption of proper care and handling of the drugs involved, by nurses, doctors and other individuals, and that such presumption is sufficient to prevail over the presumption of innocence, is in conflict with *Coffin v. United States,* 156 U. S. 432, 458; *Dalton v. United States,* 154 Fed. 461 (C. C. A. 7), and numerous State Court decisions referred to in the accompanying brief.

Also, this holding by the Circuit Court of Appeals is contrary to numerous cases which hold that a presumption cannot be applied in the face of evidence to the contrary. For example, see *Ezzard v. United States,* 7 F. (2d) 808 (C. C. A. 8), and *Heine v. United States,* 135 F. (2d) 914 (C. C. A. 6).

3. The decision of the Circuit Court of Appeals in holding that the Federal Statute involved in this case should be liberally construed is in conflict with decisions of this Court and other decisions of the Circuit Court of Appeals for the Ninth Circuit.

This Court, in *M. Kraus & Bros., Inc., v. United States,* 327 U. S. 614, 621, held that in a criminal proceeding under an act which may also afford civil relief, the provision must be applied in the same strict rule of construction that is applied to statutes defining criminal action.

In *Alberty v. United States,* 159 F. (2d) 278, the Circuit Court of Appeals for the Ninth Circuit on January 3, 1947, held that in criminal cases under the Food, Drug and Cosmetic Act, the strict rule of construction must be applied. In view of the fact that in the Ninth Circuit we have conflicting holdings by different judges of that Court, the Supreme Court should decide this question of whether

or not in criminal cases under the Food, Drug and Cosmetic Act the rule of strict construction applies.

Wherefore, your petitioners respectfully pray that this petition be granted and that a Writ of Certiorari be issued directed to the Circuit Court of Appeals for the Ninth Circuit.

R. WELTON WHANN,
ROBERT M. MCMANIGAL,
Attorneys for Petitioners.

Dated at Los Angeles, California, September 10, 1948.

IN THE

Supreme Court of the United States

October Term 1948

No.....

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET, an individual,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

BRIEF IN SUPPORT OF PETITION.

The Opinion Below.

The opinion of the Circuit Court of Appeals for the Ninth Circuit is unreported, but is reproduced in the transcript of record filed herein [R. 234, *et seq.*].

There is no opinion of the District Court.

The Judgment and Probationary Order of the District Court were filed on July 7, 1947 [R. 20-23].

Jurisdiction.

The judgment of the Circuit Court of Appeals was entered on July 16, 1948 [R. 259]. On August 10, 1948, petitioners obtained from this Court an extension of time to September 14, 1948, within which to file this petition. The Information was filed under the Federal Food, Drug and Cosmetic Act of 1938 (21 U. S. C. A. 321). The jurisdiction of this Court is invoked under Section 240(a) of the Judicial Code as amended by the Act of February 13, 1925 (28 U. S. C. A. 347).

Statement of Facts.

(a) Indoform (Counts I and II).

As stipulated [R. 14] as to Counts I and II a number of vials of "Indoform" were shipped by the petitioners on or about September 17, 1945, from Pasadena, California, to Dr. Joseph C. Bunton, Cheyenne, Wyoming. One vial was picked up as a sample by a Government inspector on or about January 24, 1946, from Dr. Bunton, and was sealed and mailed to the Food and Drug Administration, Washington, D.C., hereinafter referred to as the Administration.

The vials carried labels reading that each cubic centimeter of the drug contained three International Units of posterior pituitary.

On February 18, 1946, Arnold E. Mason, a pharmacologist and analyst of the Administration, examined the contents of the sample vial and "found practically no posterior pituitary in that product" [R. 59].

The sole evidence introduced by the Government as to whether or not this product contained the amount of posterior pituitary set forth on the label, Exhibit 4, on September 17, 1945, the date it was introduced or delivered into interstate commerce, is an *opinion* expressed by the Government's witness Mason in response to an *improper* hypothetical question, duly objected to, and which included facts not proved and which question was based on the assumed existence of facts, the existence of which were not

established by any evidence whatever in the case[1] [R. 75, 76].

The undisputed testimony of Bavouset is that he prepared the solution and that he measured out three International units of posterior pituitary for each cubic centimeter of the contents of that bottle for this particular solution [R. 110].

(b) PLURI-B (COUNTS III AND IV).

As also stipulated, a number of vials of "Pluri-B" were shipped by the petitioners on or about July 16, 1945, from Pasadena, California, to Dr. Clement Swaim, Reno, Nevada. A sample consisting of two vials was obtained by a Government inspector on or about August 30, 1945, from Dr. Swaim, and was sealed and mailed to the Administration at Washington, D. C. [R. 15].

The vials carried labels reading that each cubic centimeter of the drug contained 50 milligrams of thiamine hydrochloride.

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[1]The hypothetical question propounded to Mason and his opinion answer are:

"Q. Assuming, Mr. Mason, that this product was not exposed to excessive temperatures, that is to say, that you said was 212 degrees is the destructive temperature; and assuming the product was handled in a normal and careful manner, retained in the bottle, as Government's Exhibit No. 4, I believe; assuming which bottle you opened and conducted the test as you have testified; and, with the assumption of what you found or did not find at that time, have you an opinion as to whether or not this product contained three international units of posterior pituitary on September 17, 1945?

* * * * * * * * * *

"A. It is my opinion that the product could not have contained three units of posterior pituitary per cubic centimeter on September 17, 1945." [R. 75, 76.]

On September 24, 1945, Hubert H. Capps, a chemist of the Administration, examined the contents of one of the sample vials and testified that he found it contained approximately only 33 milligrams of thiamine hydrochloride per cc. [R. 100].

The sole evidence introduced by the Government as to whether or not this product contained the amount of thiamine hydrochloride set forth on the label, Exhibit 7, on July 16, 1945, the date it was introduced or delivered into interstate commerce, is an *opinion* expressed by the Government witness Capps in response to an *improper* hypothetical question, and which included facts not proved and which question was based on the assumed existence of facts, the existence of which were not established by any evidence whatever in the case[2] [R. 100, 101].

Bavouset testified with respect to how the Pluri-B solution, Exhibit 6, was made, that he probably made the solution himself, and that at the time the solution was bottled, it had the full strength and potency that is set forth on the label, Exhibit 7 [R. 114, 115].

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[2]The hypothetical question propounded to Capps and his answer thereto are quoted as follows:

> "Q. Now, assuming that the product received ordinary and reasonable care, and was not exposed to excessive heats, such as heats any more than would be normal from shipping and the weather, and basing upon what you found on September 24, 1945, the amount of the B-1 or thiamine chloride that you found, have you an opinion as to what percentage or what amount that product, substance, or solution had on or about July 16, 1945, the date it was originally shipped?
>
> "A. I believe it did not contain as much as 50 milligrams; not more than 33." [R. 100, 101.]

(c) PLURI-B (COUNT VII).

It was stipulated that a number of vials of "Pluri-B" were shipped by the petitioners on or about June 18, 1946, from Pasadena, California, to Dr. P. M. Ryerson, Phoenix, Arizona. A sample consisting of six vials was picked up by a Government inspector on or about July 12, 1946, from Dr. Ryerson, and was sealed and forwarded to the Administration at Washington, D.C., by railway express [R. 15, 16].

On July 23, 1946, Dr. Frank H. Wiley of the Administration examined the contents of the sample vials and found that they were badly contaminated with undissolved material [R. 34].

The sole evidence introduced by the Government as to whether or not this product was contaminated on June 18, 1946, the date it was introduced into interstate commerce, is an *opinion* expressed by the Government's witness Wiley in response to an *improper* hypothetical question, duly objected to, which did not include a sufficient factual basis to support an opinion in that no mention whatever was made of the conditions to which the drug had been subjected to after shipment from Pasadena, California, on June 18, 1946, until the date of examination, July 23 1946.[3]

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[3]The hypothetical question propounded to Wiley and his answer thereto are quoted as follows:

"Q. By Mr. Neukom: Dr. Wiley, taking the two vials, part of Government's Exhibit No. 1, which I understand you examined about six weeks after the shipment in question here, from your knowledge of sterile solutions and from your observation of sterile solutions, your experience, are you able to express an opinion to this court as to whether or not the contents of those two vials, Government's Exhibit 1, did contain the undissolved particles you noticed there then as of the date

Bavouset's undisputed testimony is that there was no precipitate in the bottles which were shipped to Dr. Ryerson in Phoenix, Arizona, on June 18, 1946 (which shipment included the two vials, Exhibit 1) at the time the product was made, that there was no precipitate in those bottles at the time the product was shipped, that a very careful inspection was made at the time the bottles were shipped, and that control batches were kept until after the material had been shipped [R. 118, 119].

Mrs. Smiley testified she was in charge of the Shipping Department, that she examined the solutions in the vials of Exhibit 1 by means of an inspection lamp to be sure there were no particles in them, that at the time she selected and tagged them there were no particles in these vials when she examined them for that purpose, and that she remembered this particular shipment because it was for 50 bottles and it was unusual to have an order that large [R. 120 to 122].

STABILITY OF PETITIONERS' PRODUCTS.

The undisputed evidence is that petitioners' drugs will change in potency if not kept under proper conditions of temperature, light, etc., if not properly handled, or if cer-

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they were shipped, namely, on or about June 18, 1946? Your answer is yes or no. A. Yes.

* * * * * * * * * *

Q. By Mr. Neukom: Will you please relate your opinion? A. From experience with these materials and from general information of so-called super-saturated solutions, of which this is an example, I would say that this undissolved material was undoubtedly present on June 18th when the material was shipped. There is only one external factor of which I know that would hasten or increase the crystalization of this material, and that would be refrigeration. I doubt very much if the mail bag in which this material was transmitted to Washington was in a refrigerator car." [R. 41, 42.]

tain other types of materials, such as oxidizing materials, materials which change the nature of the solvent, etc. are added to the products.

Dr. Icke's testimony is that thiamine hydrochloride is not stable at temperatures above 100 to 120 degrees Fahrenheit and that if the bottles, Exhibit 6, "had been setting in the sunlight so that the temperature got up that high, or any other factor which might have elevated the temperature, it might have deteriorated" [R. 185].

This product, Exhibit 6, was shipped from Pasadena, California, on July 16, 1945, to Reno, Nevada, was picked up by the Government inspector on August 30, 1945, and was sent to Washington, D. C. The product was shipped and handled during the heat of the summer and may well have been exposed to temperatures in excess of 100 degrees during both shipments and while in Reno.

Dr. Icke further testified that thiamine hydrochloride can be destroyed very rapidly if the solution is brought towards neutrality or on the alkaline side, in that the solution must be kept acid in order to be stable [R. 159], that it is susceptible to destruction by the presence of sulfites and by oxidation, and that in the presence of any such compounds, any temperature above normal would speed the rate of destruction [R. 159]. Bavouset's testimony is in accord [R. 115, 149, 150].

The Government witness Capps testified that thiamine hydrochloride is stable except when exposed to "extreme high temperatures," and that "heats any more than would be normal from shipping and the weather" would be excessive [R. 100, 101].

With respect to the undissolved material in Exhibit 1 (Count VII), the Government witness Wiley stated that temperatures slightly above freezing would hasten or increase precipitation [R. 42]. Bavouset testified that he has observed that riboflavin precipitates upon fluctuation of temperature [R. 145]. Dr. Icke testified that riboflavin might precipitate if the doctor added other materials which changed the nature of the solvent, and that temperature affects its stability, particularly in the presence of oxidizing materials or any substance which increased the alkalinity of the solvent [R. 171, 172].

ADDITION OF OTHER MATERIALS INTO PRODUCTS.

The evidence shows that doctors insert hypodermic needles into the caps of these bottles for withdrawing the solutions from them, and that it is possible and likely that the potencies of the solutions will be changed because of the presence of isopropyl alcohol which some doctors use for sterilizing hypodermic needles [R. 161-163].

The Government *stipulated* that doctors deliberately insert other things into bottles to make a different combination of a product [R. 168].

Specification of Errors.

1. The Circuit Court of Appeals for the Ninth Circuit erred in holding that petitioners are guilty of the crime of introducing into interstate commerce drugs which are adulterated and misbranded even though there is no evidence to prove that the drugs when tested by the government expert witnesses were in the same condition

as when the drugs were *introduced* into interstate commerce by petitioners, and there is no evidence showing how the drugs were cared for or handled, or the conditions to which the drugs were subjected between the time they were shipped by petitioners and the time they were picked up by government inspectors.

2. The Circuit Court of Appeals for the Ninth Circuit erred in holding that in a criminal prosecution under the Federal Food, Drug and Cosmetic Act charging the crime of introducing into interstate commerce drugs which are adulterated and misbranded, the presumption that the acts of private individuals are rightfully done when applied to the handling of drugs by doctors, nurses and others, prevails over the presumption of innocence, even in the face of evidence that the drugs were not adulterated and misbranded at the time of shipment.

3. The Circuit Court of Appeals for the Ninth Circuit erred in holding that in a criminal prosecution based on a charge of violating the Federal Food, Drug and Cosmetic Act, such Act should be liberally construed.

4. The Circuit Court of Appeals for the Ninth Circuit erred in holding petitioners guilty of the crimes charged in Counts I to IV and VII of the Information.

Statutes Involved.

The pertinent portions of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, 21 U. S. C., Sec. 301 *et seq.*, are set forth in Appendix B.

ARGUMENT.

1. **The Circuit Court of Appeals for the Ninth Circuit Erred in Holding That Petitioners Are Guilty of the Crime of Introducing Into Interstate Commerce Drugs Which Are Adulterated and Misbranded Even Though There Is No Evidence to Prove That the Drugs When Tested by the Government Expert Witnesses Were in the Same Condition as When the Drugs Were Introduced Into Interstate Commerce by Petitioners, and There Is No Evidence Showing How the Drugs Were Cared for or Handled, or the Conditions to Which the Drugs Were Subjected Between the Time They Were Shipped by Petitioners and the Time They Were Picked Up by Government Inspectors.**

The evidence establishes that the drugs involved are unstable and if not properly handled and cared for will deteriorate and change in potency and precipitates or undissolved matter will form therein.

There is no evidence either by testimony, document, or stipulation, which shows how the drugs were handled or cared for, or the conditions to which they were subjected after petitioners delivered them into the hands of the shippers and until they arrived at the Federal Food and Drug Administration in Washington, D. C.; or is there any other evidence showing that the goods when tested by the Government were in the same condition as when shipped by petitioners.

Petitioners are guilty of a crime only if the drugs were adulterated or misbranded at the time they were *introduced* into interstate commerce. The judgment of the Court below is in conflict with the decisions of other

Circuit Courts, Courts of inferior jurisdictions and the criminal law, which requires that an article before it can be introduced in evidence must be shown by at least some evidence to be unchanged in any respect material to the issues involved in the trial.

The evidence herein does not show that the drugs when tested by the Government expert witnesses were in the same condition as when shipped. The evidence does not show that the drugs did not change *after* petitioners shipped the drugs. The Court's below holding of guilt in spite of the absence of this type of evidence is the very basis on which the aforesaid conflict arises.

In *United States v. S. B. Penick & Co. et al.*, 136 F. (2d) 413, which is a case arising under the Federal Food, Drug and Cosmetic Act, the Circuit Court of Appeals for the Second Circuit upheld the conviction by the Lower Court and rejected the argument of appellants that the Government had not proved that the samples tested by the Government were the same drugs as introduced into interstate commerce, because the Circuit Court found that there was some evidence that the drugs were properly handled and care for. In that case the Court said:

> "* * * It is true that before a physical object connected with the commission of a crime can properly be admitted in evidence, there must be a showing that such object is in substantially the same condition as when the crime was committed. 2 Wharton, Criminal Evid., 11th Ed., §757. But there is no hard and fast rule that the prosecution must exclude all possibility that the article may have been tampered with. See Lestico v. Kuehner, 204 Minn. 125, 283 N. W. 122, 125. In each case the trial judge before he admits it in evidence must be satisfied that in

reasonable probability the article has not been changed in important respects. Wigmore, Evidence, 3rd Ed., §437(1); 32 C. J. S., Evidence, §607. In reaching his conclusion he must be guided by the nature of the article, the circumstances surrounding the preservation and custody of it, and the likelihood of intermeddlers tampering with it. Here the samples were taken in the ordinary course of business for the very purpose of being retained as samples; they were put in the usual place where samples were kept to remove them from accident or meddling and there they remained, so far as appear, undisturbed. We think this showing was sufficient to justify admission in evidence of the bottles and their contents and that it was for the jury to decide how likely it was that some other substance had been substituted for what was originally put in the bottles. * * *" (p. 415.)

Epitomizing the foregoing the law of the Second Circuit is in effect that there *must* be a showing that the object is in substantially the same condition as when the crime was committed; that although there is no hard and fast rule that *all* possibility of tampering must be excluded, the judge *must* be satisfied that in reasonable probability the article *has not changed in important respects;* and in reaching his conclusion *he must be guided by the nature of the article, the circumstance surrounding the preservation and custody of it, and the likelihood of intermeddlers tampering with it.*

Another case which is in conflict with the decision of the Circuit Court of Appeals in this case is *United States v. Buffalo Pharmacal Co., Inc.*, 131 F. (2d) 500, wherein the Circuit Court of Appeals for the Second Circuit upheld the conviction of one of the appellants because there was *some evidence* to indicate that the bottle of digitalis

in question had been properly cared for. In that case evidence was introduced by appellants to show that digitalis, if not properly cared for, might deteriorate. The Government, to meet this evidence showed that the goods were property cared for. The Court said:

> "* * * While cross examination brought out that digitalis tablets may deteriorate in potency by lapse of time if not properly stored, *there was some testimony to indicate that the bottle in question had been properly cared for.* We cannot say that the evidence was insufficient to support the verdict of adulteration and misbranding." (Italics added.) (P. 502.)

In view of this clear conflict between the decisions of the Ninth Circuit and the Second Circuit this question should be decided by this Court.

In *Novak v. District of Columbia,* 49 A. (2d) 88, the Court stated at page 90:

> "* * * We agree that it was still incumbent upon the government to prove that the specimen taken from defendant and the one analyzed by the chemists, and reported on in court, were the same and were in substantially the same condition when tested as when taken. * * *"

Even in civil cases the same rule applies. In *Gutman v. Industrial Com.,* 71 Ohio App. 383, 50 N. E. (2d) 187, the Court held at pages 385 and 386:

> "When an object, article, machine, machine part, tool, weapon or similar concrete thing is to be used in

evidence to prove a fact with which it is related as of a previous time or event, it is not competent evidence unless it is first shown to be substantially in the condition as of the time or event to which it is claimed to be related. This principle of law is so well established as a rule of evidence that we deem it unnecessary to refer to many authorities. * * *

" 'It must appear, as a preliminary to the introduction of any object in evidence, that it has not sustained any substantial change by reason of lapse of time or otherwise, since the time in issue.' 20 American Jurisprudence, 602, Section 719."

Furthermore the civil case of *Lestico v. Kuehner,* 204 Minn. 125, 283 N. W. 122, which the Court below quotes as supporting its opinion [Court's Opinion, R. 245], as a matter of fact supports petitioners' position, for it says:

"If changes had destroyed its identity or had made the object wholly worthless or of questionable value as evidence, an entirely different situation would have been presented." [p. 125].

32 Corpus Juris Secundum, Section 607, at pages 457-458, is in accord with the Second Circuit cases and reads in part as follows:

"In order that an article may be introduced *it must be satisfactorily identified,* and *it must also be shown* to the satisfaction of the Court that *no such substantial change in the article exhibited as to render the evidence misleading has taken place.* * * *." (Italics added.)

> *"Samples.* Samples are admissible on an issue as to the properties or qualities of the substance or articles involved in the case. The samples must be sufficiently identified as to their source, and must reflect the condition of the substance or articles as of the time involved in the issues. * * *"

The Court below in its opinion [R. 247] quotes the following excerpt from 32 C. J. S., Section 607, which we submit supports our position rather than that of the Court below:

> "However, it is not necessary that the article be *identically* the same as at the time in controversy. It is unnecessary to show an absence of tampering on the part *of every person* through whose hands the article has passed; as long as the article can be identified it is immaterial in how many or in whose hands it has been. A direct statement that the article was in the same condition at the time of an occurrence as at a subsequent time is not required *if it sufficiently appears that it must have been in substantially the same condition."* (Italics added.)

We agree that the article need not be *identical* and that a showing of the absence of tampering on the part *of every person* need not be shown; but we do assert, and the above excerpt supports our assertion, that the article must be shown to be in substantially the same condition as when the crime occurred.

2. The Circuit Court of Appeals for the Ninth Circuit Erred in Holding That in a Criminal Prosecution Under the Federal Food, Drug and Cosmetic Act Charging the Crime of Introducing Into Interstate Commerce Drugs Which Are Adulterated and Misbranded, the Presumption That the Acts of Private Individuals Are Rightfully Done When Applied to the Handling of Drugs by Doctors, Nurses and Others, Prevails Over the Presumption of Innocence, Even in the Face of Evidence That the Drugs Were Not Adulterated and Misbranded at the Time of Shipment.

As we have shown in the preceding section, one of the indispensable elements of proof necessary to convict petitioners is that the drugs when tested by the government were in the same condition as when *introduced* into interstate commerce by petitioners. To establish this fact the government should have, but failed to, introduce evidence of proper handling and care of the drugs after shipment by petitioners.

The Court below must have concluded that such showing was necessary but absent from the evidence, because to fill this deficiency in the government's proof, the Court below invoked the presumption of rightfulness of the acts of private individuals, applying this presumption to establish that the drugs were properly handled and cared for by the doctors, nurses, and other private individuals after shipment by petitioners.

No such presumption can be invoked against an accused to overcome the presumption of innocence and thus obtain a conviction. The Circuit Court's holding is directly contrary to the well established law that the presumption of

innocence is a conclusion drawn by the law requiring the accused to be acquitted unless he is proven to be guilty by evidence establishing accused guilty beyond a reasonable doubt.

In *Coffin v. United States,* 156 U. S. 432, 458, the Supreme Court said:

> "* * * 'Now, the presumption of innocence is a conclusion drawn by the law in favor of the citizen, by virtue whereof, when brought to trial upon a criminal charge, he must be acquitted, unless he is proven to be guilty. In other words, this presumption is an instrument of proof created by the law in favor of one accused, whereby his innocence is established until sufficient evidence is introduced to overcome the proof which the law has created.' "

The lower Court's holding is in conflict with the well established law that as between conflicting presumptions such as these, that which is in favor of innocence prevails.

In *Dalton v. United States,* 154 Fed. 461, the Circuit Court of Appeals for the Seventh Circuit held that the presumption of continuance of a fact cannot prevail as against the presumption of innocence. The opinion of the Court reads in part as follows:

> "* * * 'the inference or presumption of continuance arising from the facts and circumstances proven' is inapplicable. as we believe, in any view of the strength of 'the presumption of innocence, as evidence in favor of the accused, introduced by the law in his behalf' (Coffin v. United States, 156 U. S. 432, 458, 460, 15 Sup. Ct. 394, 39 L. Ed. 481), under these changed conditions. * * * Under the established rule of our criminal law, however, as well defined in Coffin v. United States, *supra,* the 'presumption of in-

nocence is an instrument of proof created by the law in favor of the accused,' and the presumption that the accused would not remain in the concern when it turned into a criminal course would set aside or overcome the assumed inference of fact relied upon." (p. 463.)

Even the strongest of presumptions which prevail in civil cases cannot in a criminal prosecution prevail as against the presumption of innocence.

The presumption of innocence in a criminal trial prevails against the following presumptions:

The presumption of delivery of an instrument arising from the fact of possession by him to whom delivery must be made, *People v. Scott,* 22 Cal. App. 54, 133 Pac. 496, 499; the presumption of ownership arising from possession, *State v. Roswell,* 153 Mo. App. 338, 133 S. W. 99; the presumption of authority arising from an agency relationship, *State v. Priebe,* 198 Iowa 609, 199 N. W. 276; the presumption of a woman's chastity, *Commonwealth v. Whittaker,* 131 Mass. 224; the presumption that the deceased person did not take his own life, *People v. Creasy,* 236 N. Y. 205, 140 N. E. 563; the presumption that packages from certain consignors to certain consignees contained articles which the consignees expected to receive from the consignors, *Heard v. State,* 255 S. W. 177; and the presumption that a check was made on the date and at the place stated therein, *State v. Wiedenfeld,* 282 N. W. 621, 229 Wis. 563.

In the case of *State v. Shelley,* 166 Mo. 616, 66 S. W. 430, the Court held that in a prosecution for falsely impersonating an elector, the book of registration, in which the name of the party personated appears as a voter, is not

prima facie evidence that such person was an elector and entitled to vote in the precinct, sufficient to support a conviction, since the presumption that the registration proceedings were regular cannot overcome the presumption of innocence. The decision of the Court reads in part as follows:

> "* * * In circumstances such as here presented, the establishment of inferences, however strong, or probabilities, however great, will not warrant a conviction. The doctrine of chance does not apply here. * * * And the burden was on the state to establish by something more than a mere presumption—to establish beyond a reasonable doubt—that Joseph Conley was an elector of the particular precinct alleged in the indictment at the time Dan Shelley is charged with having personated him." (p. 431).

In *Nichols v. Mutual Life Insurance Co. of New York,* 178 Tenn. 209, 156 S. W. (2d) 436, the Court held that in a criminal case the presumption of innocence is stronger than that against suicide. The Court said:

> " 'It is contended the rules of evidence are the same in civil and criminal cases. Such is the general rule, but it does not follow, because the rule is the same, that presumptions applicable in the one are always applicable in the other, for an antagonistic presumption may exist, and does, in criminal cases; that is, the innocence of the defendant. *That presumption of innocence does not allow the presumption of any fact against it.* So the presumption that a deceased did not commit suicide cannot be applied in criminal cases against the presumption of innocence.' " (Italics added.) (156 S. W. (2d) 439.)

In *State v. Roswell,* 153 Mo. App. 338, 133 S. W. 99, the Court held that the presumption of accused's innocence of stealing money of a particular person cannot be overthrown by a presumption that that person owned the money. The Court said:

> "* * * Such would be all-sufficient in a civil case; but this is not true in a criminal proceeding, where *the burden is on the state to prove every element of the offense charged* beyond a reasonable doubt to the contrary. The ownership of the $10 bill and not the pocketbook is the question with which the court is concerned, and such is an essential element to the offense of larceny; for it is the bill that is charged to have been stolen.
>
> "Until the ownership is shown by something more than a mere presumption of law to the effect that possession is *prima facie* evidence of ownership, the matter is repelled and overcome by the presumption of innocence which attends the accused at all times throughout the trial. A valid distinction obtains with respect to the force and effect of such presumptions invoked by the state in a criminal proceeding and those which may be invoked in civil actions. The Anglo-Saxon love of liberty culminates in the doctrine that all persons are presumed innocent of the offense charged until such presumption is overcome by showing a state of facts or circumstances which afford a legitimate inference to the contrary. As a rule, therefore, one may not be convicted upon a mere *prima facie* case being established through the medium of presumptions which are raised by the law; for one presumption of that character will not be allowed to overthrow or destroy the effect of another. * * *" (Italics added.) (p. 100.)

The Court below has invoked the presumption of rightfulness in the face of testimonial evidence establishing that the drugs when shipped were not adulterated or misbranded; and the Court's decision is thus in further conflict with the law that there can be no presumption contrary to an established fact.

Petitioner Bavouset's undisputed testimony is that he compounded the "Indoform," Exhibit 3 (Count I), that he measured out three International units of posterior pituitary for each cubic centimeter for this particular solution [R. 110], that he probably combined the contents of the bottle, Exhibit 6 (Count III) [R. 114], and that at the time the solution was made it had the full strength and potency that is set forth on the label [R. 115].

With respect to Count VII, the undisputed positive testimony of both Mrs. Smiley and Bavouset is that both of the vials, Exhibit 1 (Count VII), were carefully inspected at the time of shipment and that they contained no precipitate or undissolved material at that time.

The decision in this case is contrary to the law as established in the Sixth and Eighth Circuits and numerous state courts.

As stated in *Heike v. United States,* 135 F. (2d) 914 (C. C. A. 6) at page 917:

> "* * * There can be no presumption contrary to an undisputed fact. The fact negatives the presumption."

In *Ezzard v. United States,* 7 F. (2d) 808 (C. C. A. 8), the Circuit Court of Appeals, in reversing a conviction held in part as follows (at pp. 811 and 812):

> "Presumptions or inferences of fact are not evidence, they are the result of evidence, and are raised on circumstances to supply the place of actual proof; when substantial proof is made contrary to the fact presumed, the presumption is rebutted. * * *"
>
> "In State v. Jones, 64 Iowa, 349, 17 N. W. 911, there was conviction for murder. The defense was insanity, in support of which there was some evidence. The trial court had instructed the jury that if the evidence shows that the insanity of defendant was probable, that evidence would not overcome the presumption of sanity. On that subject the court said:
>
> " 'The presumption is not to be weighed against any measurable amount of evidence.'
>
> "Largen v. State, 76 Tex. 323, 13 S. W. 161, was a civil action. The court, in commenting upon a presumption relied upon by one of the parties, said:
>
> " 'Presumptions cannot be indulged in opposition to facts which show that the fact sought to be established by presumption can have no existence.' "

In *Hall v. Commonwealth,* 178 Va. 22, 16 S. E. (2d) 304, 305, the Supreme Court of Appeals of Virginia said:

> " 'Presumptions are indulged to supply the place of facts; they are never allowed against ascertained and established facts. When these appear, presumptions disappear.' Moore on Facts, section 545."

III.

The Circuit Court of Appeals for the Ninth Circuit Erred in Holding That in a Criminal Prosecution Based on a Charge of Violating the Federal Food, Drug and Cosmetic Act, Such Act Should Be Liberally Construed.

The Court below held "The Act is remedial, and should be liberally construed so as to carry out its beneficent purposes" [R. 240] and that Court did not feel disposed to depart from the "generous norm of interpretation" in which it construed the Act in the civil case of *Research Laboratories, Inc., v. United States,* 167 F. (2d) 410, 421. This holding is contrary to the decisions of this Court and other decisions of the Ninth Circuit Court of Appeals.

This Court, in *M. Kraus & Bros., Inc., v. United States,* 327 U. S. 614, 621, 66 S. Ct. 705, 707, in construing in a criminal proceeding the Emergency Price Control Act of 1942, stated:

> "This delegation to the Price Administrator of the power to provide in detail against circumvention and evasion, as to which Congress has imposed criminal sanctions, creates a grave responsibility. In a very literal sense the liberties and fortunes of others may depend upon his definitions and specifications regarding evasion. Hence to these provisions must be applied the same strict rule of construction that is applied to statutes defining criminal action * * *" (327 U. S. 614, 621.)

In the case of *Alberty v. United States,* 159 F. (2d) 278, 280, which is a decision of another group of judges of the Ninth Circuit, the Ninth Circuit holds that in a criminal prosecution the Federal Food, Drug and Cosmetic Act should be strictly construed and follows the

Supreme Court ruling in *M. Kraus & Bros., Inc., v. United States, supra.* The Ninth Circuit, in *Alberty v. United States,* refused to follow the rule laid down in certain other cases and said:

> "These three cases were civil proceedings and not criminal prosecutions. They construe the Act liberally. * * *"

The Court below cited the case of *United States v. Dotterweich,* 320 U. S. 277, as its authority for its liberal construction of the Act. In the above-mentioned case, this Court merely held that the Act should "infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words," and not that the Act should be liberally construed in a criminal prosecution.

A careful consideration of the lower Court's opinion leads us to the conclusion that the failure of the lower Court to apply the strict rule of construction which should be applied in criminal prosecutions led the lower Court into its numerous errors. It is clear that the Court below has failed to draw the distinction between civil and criminal cases in respect to the degree or quantity of evidence necessary to find the accused guilty. The case of *State v. Shelley,* 166 Mo. 616, 66 S. W. 430, sets forth the situation very nicely as follows:

> "* * * Greenleaf says: 'A distinction is to be noted between civil and criminal cases in respect to the degree or quantity of evidence necessary to justify the jury in finding their verdict for the government. In civil cases their duty is to weigh the

evidence carefully, and to find for the party in whose favor the evidence preponderates, although it be not free from reasonable doubt. But in criminal trials, the party accused is entitled to the benefit of the legal presumption in favor of innocence, which in doubtful cases is always sufficient to turn the scale in his favor. It is therefore a rule of criminal law that the guilt of the accused must be fully proved * * *" (66 S. W. 430, 431.)

The Court below apparently felt that when once the Government introduced its evidence as to the tests it made of the drugs that the burden of proof then shifted to petitioners. The Court below said:

"The appellants have not pointed out, nor have we been able to find, a single scintilla of evidence in the record to indicate that any of the vials were mishandled by a single postal clerk, expressman, doctor, nurse, Government analyst, Administration mail clerk, or any one else who had any connection with the sealing, labeling, consignment, transmission, unwrapping, unsealing, or testing of the products in question.

"The only suggestions of mishandling are in the form of dire possibilities conjured up by resourceful counsel. But possibilities are not proof." [R. 250.]

This is not in accordance with the law as defined by this Court in *Lilienthal's Tobacco v. United States*, 97 U. S. 237, 24 L. Ed. 901. The holding of this case is that the burden of proof never shifts in a criminal case.

In *Ezzard v. United States,* 7 F. (2d) 808 (C. C. A. 8), the Court, in reversing a conviction held in part as follows:

> "Presumptions or inferences of fact are not evidence, they are the result of evidence, and are raised on cricumstances to supply the place of actual proof; when substantial proof is made contrary to the fact presumed, the presumption is rebutted. In civil cases they may sometimes fix the *onus probandi,* but not so in criminal on the main issue. There, on a plea of not guilty, the burden and quantum of proof to establish the *corpus delicti* and defendant's guilt never shifts. Lilienthal's Tobacco v. United States, 97 U. S. 237, 266, 267, 24 L. Ed. 901; David v. United States, 160 U. S. 469, 487, 40 L. Ed. 499. Where possession is the offense charged, the *corpus delicti,* and the defendant's possession is shown, a verdict of guilty will stand in the absence of proof establishing an innocent possession. Feinberg v. U. S. (C. C. A.), 2 F. (2d) 955. ***But the writer is of opinion that a prima facie case is unknown in criminal procedure. In no condition of proof is it permissible to instruct a jury that it had become the duty of defendant to establish his innocence to obtain an acquittal*** * * *." (p. 811.) (Italics added.)

The prosecution can only prevail upon the strength of its own case, not the weakness of that of defendant. (*United States v. Laffman* (C. C. A. 3), 152 F. (2d) 393.) That the Court failed to follow this rule of law is clearly shown by the section of the Court's opinion entitled, "7. The Appellants' Admitted Lack of Testing Equipment" [R. 258].

Conclusion.

Wherefore, it is submitted that this case is one calling for the exercise by this Court of its supervisory powers and that to such end a writ of certiorari should be granted to review the decision of the Circuit court of Appeals for the Ninth Circuit and finally reverse it.

Respectfully submitted,

R. WELTON WHANN,
ROBERT M. MCMANIGAL,
Attorneys for Petitioners.

Dated at Los Angeles, California, September 10, 1948.

APPENDIX A.

CLERK'S FILE COPY.

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In the District Court of the United States in and for the Southern District of California Central Division.

Honorable Charles C. Cavanah, Judge Presiding.

United States of America, Plaintiff, vs. Harlow S. Boyle and Charles E. Boyle, Jr., Defendants. No. 18,-940—Crim.

REPORTER'S TRANSCRIPT OF OPINION OF THE COURT.

Los Angeles, California, February 21, 1947.

Appearances:

For the Plaintiff: Homer H. Bell, Esq., Assistant United States Attorney.

For the Defendants: Howlett & Elson, by: Eugene H. Elson, Esq.

Los Angeles, California, Friday, February 21, 1947, 10:00 A. M.

The Court: Gentlemen, after hearing the arguments of counsel, I do not deem it necessary to state at length what the evidence specifically discloses.

The information in this case charges the defendants in nine counts with violation of certain provisions of the Federal Food and Drug Act.

The burden of proof rests upon the government to establish, beyond a reasonable doubt, by competent evidence, such violations. The defendants are presumed to be innocent until they are proven guilty as charged. Such a reasonable doubt is one which is reasonable in

view of all of the evidence, and which causes one to hesitate, in the ordinary affairs of life, and to be fully satisfied of the defendants' guilt.

The Act upon which the information is based makes it an offense for one to adulterate or misbrand food and drug products, and it has to exist at the time of shipment and delivery for introduction into interstate commerce, and not thereafter.

So with these thoughts in mind we are required to approach the consideration of the evidence in determining the guilt or innocence of the defendants. The particular manner of shipment into interstate commerce, and the introduction, or delivery for introduction into interstate commerce of the drug that is charged to be adulterated or misbranded must be considered when applied to the Act. There seems to be a conflict in the evidence as to the condition of the product at the time of shipment, and whether the representations made on the labels were false.

Briefly stated, the defendants were engaged in the distribution of drug products and vitamin preparations, and caused the same to be transported to the place referred to in the information, and sold. They were there seized by government agents, and were transported to the City of Washington, D. C., where an analysis was made by the government agent, and the products, as claimed by the government, were not, as disclosed by the analysis, up to the potency as represented.

The defendants assert that at the time of the shipment the products were not below potency, as represented, and that there was no adulteration or misbranding. The in-

quiry then is, after all of the evidence is considered together, which one of the contentions is established?

We must not forget that in determining that issue of fact we should consider all of the conditions and circumstances from the time of manufacture, the manner of shipment, the time, and all circumstances as to heat, and so forth, as bearing upon the condition the products were in, and whether the representations made were correct, as represented on the labels, or whether they were below such potency. After viewing the evidence we are confronted with a conflict as to the results given in support of the conclusions of the witnesses, and many factors are given which enter into these opinions.

The defendants showed by a number of qualified witnesses that the contents included the samples from a drug company, I believe in the State of New York, and which they claim were of the required potency. They say that loss in potency cannot be ascertained unless you know all the conditions, and the conditions must be standard. They must be kept under constant temperature, and if this were not done, after they reach the cities to which they are shipped, loss in potency would be possible. They say that in making these analyses, if they are not made under the same conditions present, and standard conditions, there will be uncertainty as to the potency and stability which existed prior to that date.

I realize that under this record we have such a conflict in the evidence, and confusion, that it makes it difficult for a court to determine the matter beyond a reasonable doubt, without guessing, basing it upon mere opinion, and not upon facts, applying the fundamental priciples which govern. When one is charged with the commission of a

crime, the doctrines of burden of proof and reasonable doubt should be applied.

I am unable, therefore, after considering this conflicting and confusing evidence, to reach any other conclusion than that an uncertainty exists as to the defendants' guilt on each of these counts in the information.

We cannot presume one guilty of a charge. The presumption is that he comes into court clothed with innocence, and the burden of proof is upon the government to prove to a certainty that he is guilty of the crime charged. Otherwise we would ignore the fundamental principles of our law. I cannot do that.

I am convinced, unler this evidence, that there was an opportunity which existed from the time the defendants are charged with shipping this product into interstate commerce—which is the time when the crime has to be committed—and the time it went through these different cities, to Washington, where the analysis was made by the government, and upon which the government predicates its direct proof of guilt, for conditions to be present which might have caused a change in the potency of the product as represented at the time it was shipped. We cannot presume from this analysis, made as late as March, that the potency was lower than that represented upon the labels, after we consider the conditions under which these samples were shipped.

Therefore, I have reached the conclusion, according to the principle of reasonable doubt which exists in my mind, and I find the defendants not guilty upon each of the counts of this information. Therefore they are discharged.

Mr. Bell: Does that apply to Count III in which no assay was involved, in which the strength was taken for

granted, and the statement of whether the ability of that particular item to support the androgenic therapy was involved. The defendants' representations as to the strength were taken as true. That is Count III.

Mr. Elson: The question of assay in connection with Count III, which was the androgenic substance, was not involved. Mr. Bell is correct in this. However, as I contended yesterday, and as I contend now, there was just as much of a conflict in the evidence as to whether that androgenic substance, called Hormo-gen, had therapeutic value, or whether it did not have therapeutic value.

The Court: The conclusion I have reached applies to all of these nine counts.

CERTIFICATE.

I hereby certify that I am a duly appointed, qualified and acting official court reporter of the United States District Court for the Southern District of California.

I further certify that the foregoing is a true and correct transcript of the proceedings had in the above entitled cause on the date or dates specified therein, and that said transcript is a true and correct transcription of my stenographic notes.

Dated at Los Angeles, California, this 18th day of March, A. D., 1947.

HENRY A. DEWING,
Official Reporter.

[Endorsed]: Filed Apr. 7, 1947, Edmund L. Smith, Clerk.

A true copy, Dec. 29, 1947. Attest, etc. Edmund L. Smith, Clerk U. S. District Court, Southern District of California. By Edw. F. Drew, Deputy.

APPENDIX B.

The pertinent portions of the Federal Food, Drug and Cosmetic Act of 1938, 52 Stat. 1040, 21 U. S. C., Sec. 301, *et seq.*, are as follows:

"Section 201. Definitions; generally. (21 U. S. C. 321.)

"For the purposes of this chapter—

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual."

"Section 301. Prohibited acts (21 U. S. C. 331.)

"The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded."

"Section 303. Penalties—Violation of Sec. 301. (21 U. S. C. 333.)

(a) Any person who violates any of the provisions of Section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine * * *."

"Section 501. Adulterated drugs and devices. (21 U. S. C. 351.)

"A drug or device shall be deemed to be adulterated—

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess."

"Section 502. Misbranded Drugs and Devices. (21 U. S. C. 352.)

"A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular."

IN THE

Supreme Court of the United States

OCTOBER TERM, 1949.

No. 274

PASADENA RESEARCH LABORATORIES, INC., a corporation, and RUSSELL R. BAVOUSET, an individual,

Petitioners,

vs.

UNITED STATES OF AMERICA,

Respondent.

PETITIONERS' REPLY BRIEF.

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TABLE OF AUTHORITIES CITED

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Respondent.

PETITIONERS' REPLY BRIEF.

The petition filed by petitioners herein does not, as set forth in Government's Opposition Brief, page 2, present the question of whether or not "It is necessary for the Government to disprove *every conjectural suggestion as to extraordinary handling* the products might have received from the time they were originally shipped to the time they were examined by government chemical analysts * * *." The first of the five questions presented is whether or not petitioners can be convicted "where there is no evidence to prove that the drugs when tested by the Government expert witnesses were in the same condition as when the drugs were *introduced* into interstate commerce by the accused, and no evidence showing how the drugs were cared for or handled, or the conditions to

which the drugs were subjected between the time they were *introduced* into interstate commerce by the accused and picked up by the Government inspectors?" (Petition for a Writ of Certiorari, pp. 6 and 7.)

The answer to this question when given by this Court will clear up the existing conflicts, and act as an authoritative guidepost in future prosecutions under the Federal Food, Drug and Cosmetic Act of 1938.

The decision of the Court below decides that an accused in a prosecution under the Federal Food, Drug and Cosmetic Act, may be convicted in the absence of such evidence.

This holding is in conflict with the holdings and rationale of *United States v. S. B. Penick & Co., et al.*, 136 F. 2d 413, and *United States v. Buffalo Pharmacal Co.*, 131 F. 2d 500, of the Circuit Court of Appeals for the Second Circuit, as well as the other cases referred to in Petitioners' Brief, pages 9 to 11.

Petitioners are convinced the Court below is in error; but whether right or wrong there is conflict with the Second Circuit, and this Court should decide which Circuit, the Ninth or Second, is right.

The Court below has substituted presumption for proof, and this is most clearly brought out with respect to Count VII, wherein the undisputed, uncontradicted evidence in the case as given by the petitioner Bavouset and the inspector Mrs. Smiley of the corporate petitioner establishes that at the time the vials of Exhibit 1 were shipped they did not contain any precipitate or undissolved material (Petitioners' Brief, p. 18). The Government's evidence as set forth in its Opposition Brief, page 8, is that

on August 1, 1946, Dr. Wiley found a considerable quantity of undissolved material and that in his opinion, the undissolved material was present on June 18, 1946, the date of the shipment by petitioners.

The Court below has raised its presumption contrary to an undisputed fact, and this is in conflict with the well established law that "there can be no presumption contrary to an undisputed fact. The fact negatives the presumption." (See cases in Petitioners' Brief, pp. 33 and 34.)

The indulging in such a presumption by the Court below is in conflict with the decisions of the Circuit Court of Appeals for the Sixth and Eighth Circuits, as set forth in *Heine v. United States,* 135 F. 2d 914, at page 917, a decision of the Circuit Court of Appeals for the Sixth Circuit, and *Ezzard v. United States,* 7 F. 2d 808, at pages 811 and 812, a decision of the Circuit Court of Appeals for the Eighth Circuit.

The Government has clearly set forth its burden on page 11 of its Opposition Brief, as follows:

> "* * * the burden on the Government in a criminal case is to prove all the essential elements of an offense beyond a reasonable doubt; * * *."

An element of the Government's case and one of the essential elements necessary to conviction, is proof that the drugs when tested were in the same or substantially the same condition as when they were introduced into interstate commerce by the petitioners.

The herein filed petition asks this Court to decide whether or not in a criminal prosecution of the type herein involved, the Court can supply a lacking essential element

of the offense charged by indulging in the presumption that the goods were properly handled by private individuals between the time they were shipped by petitioners and the time the goods were picked up by the Government inspectors.

In criminal cases it is proper to raise the presumption of regularity of official acts. **However, the presumption of regularity of the acts of private individuals, to our knowledge, has never been applied in a criminal case to overcome the presumption of innocence.**

The cases relied on by the Government on page 12 of its Opposition Brief do not hold that in criminal cases there is a presumption of regularity in the conduct of private individuals. It is only in civil cases that this presumption may be raised. As pointed out in Petitioners' Brief, page 30, there are many presumptions which apply in civil cases which do not apply in criminal cases.

The decision of the Court below is in conflict with the decisions pointed out in Petitioners' Brief, pages 29, 32; and we respectfully submit that this Court should decide the important question of whether in a criminal case under the Federal Food, Drug and Cosmetic Act of 1938 the presumption of regularity of the acts of private individuals should or should not prevail over the presumption of innocence.

The Government, on page 9 of its Opposition Brief, pointed out the difficulty in proving its case should this Court decide that it is incumbent in cases of this nature

for the Government to show that the drugs when tested were in the same condition as they were when shipped. We respectfully submit that difficulty of proof does not excuse the Government from proving *all* elements of the offense charged nor of proving its case beyond a reasonable doubt.

In conclusion we respectfully submit that the petition presents a number of important questions which have not been but which should be decided by this Court, and we sincerely hope that the petition for a writ of certiorari will be granted so that the questions may be decided.

Respectfully submitted,

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Attorneys for Petitioners.

Dated at Los Angeles, California, October 19, 1948.

INDEX

CITATIONS

In the Supreme Court of the United States

OCTOBER TERM, 1948

No. 274

PASADENA RESEARCH LABORATORIES, INC., A CORPORATION, AND RUSSELL R. BAVOUSET, PETITIONERS

v.

UNITED STATES OF AMERICA

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE NINTH CIRCUIT

BRIEF FOR THE UNITED STATES IN OPPOSITION

OPINION BELOW

The opinion of the Court of Appeals (R. 234-259) has not yet been reported.

JURISDICTION

The judgment of the Court of Appeals was entered July 16, 1948 (R. 260). On August 10, 1948, Chief Justice Vinson granted an extension of time to September 14, 1948, to file a petition for a writ of certiorari. The petition was filed September 13, 1948. The jurisdiction of this Court

is invoked under 28 U.S.C. 1254(1). See also Rules 37(b)(2) and 45(a), F.R. Crim. P.

QUESTION PRESENTED

Whether, in a prosecution for introducing adulterated and misbranded drugs into interstate commerce in violation of the Federal Food, Drug, and Cosmetic Act of 1938, it is necessary for the Government to disprove every conjectural suggestion as to extraordinary handling the products might have received from the time they were originally shipped to the time they were examined by Government chemical analysts, there being no evidence that they were handled in any way other than the usual course of business.

STATUTE INVOLVED

The Federal Food, Drug and Cosmetic Act of June 25, 1938, c. 676, 52 Stat. 1040, 21 U.S.C. 301 et seq., provides in part:

> SEC. 201. For the purposes of this Act—
>
> * * * * * *
>
> (n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the condi-

tions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

* * * * * *

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

* * * * * *

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than $1,000, or both such imprisonment and fine * * *.

* * * * *

SEC. 501. A drug or device shall be deemed to be adulterated—

* * * * * *

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

* * * * * *

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

STATEMENT

A seven count information, charging interstate shipments of misbranded and adulterated drugs,

in violation of the Federal Food, Drug, and Cosmetic Act, was filed against petitioners in the District Court for the Southern District of California (R. 2-12). Petitioners waived a jury trial (R. 17) and they were found guilty by the court and sentenced on counts 1, 2, 3, 4 and 7, and were acquitted on counts 5 and 6 (R. 20-21). The interstate shipments were admitted by stipulation (R. 14). The Government's evidence as to the various counts may be summarized as follows:

Counts 1 and 2. These counts charged that petitioners introduced into interstate commerce a quantity of an adulterated (count 1) and misbranded (count 2) drug called "Sterile Indoform," the labels of which represented that each cubic centimeter contained three International Units of posterior pituitary and one grain of thyroid substance, whereas in fact the drug contained no thyroid substance and less than three units of posterior pituitary (R. 2-5). Petitioner Bavouset admitted that the drug contained such small quantities of posterior pituitary as to be immeasurable (R. 143-144). Arnold E. Mason testified that on February 18, 1946, as part of his duties as a pharmacologist and analyst with the Food and Drug Administration in Washington, D. C. (R. 57), he analyzed samples of the drug which a Food and Drug Inspector had previously collected from the doctor in Cheyenne, Wyoming, to whom petitioners had shipped a number of vials

on September 17, 1945 (R. 59, 14). Using the accepted tests (R. 80-82), he ascertained that the drug contained no measurable quantity of posterior pituitary (R. 59, 74). He further testified that posterior pituitary would remain stable and continue to be effective for many months and even years (R. 74) unless it is boiled at 212° Fahrenheit for five or six hours (R. 73-74). He stated that when he received the sample, the vial was full and the rubber stopper or cork was protected with a celluloid seal around it, and that it appeared as if it had never been opened (R. 215, 79-80). It was his opinion that at the time of shipment, five months before his analysis, the drug could not have contained three units of posterior pituitary per cubic centimeter (R. 75-76). After conducting his test, without tampering with or adding anything to the product, Mason sent the vial to San Francisco for further analysis (R. 77). Mr. Buell, a chemist with the Food and Drug Administration in San Francisco (R. 84), testified that he analyzed the contents of the vial of Indoform on March 27, 1946 (R. 85-86), and found that it contained no organically combined iodine (R. 89), the distinguishing, active constituent of thyroid (R. 87). He testified that thyroid is an extremely stable substance (R. 89-90), and in his opinion the sample of Indoform he examined could not possibly have contained any organically combined iodine when it was shipped by petitioners (R. 90).

Petitioner Bavouset admitted that the product contained no organically combined iodine (R. 110-111), but contended that the legend on the label that it contained "Thyroid Substance 1 gr." was rendered not misleading by the further statement thereon that (R. 63):

> This preparation does not contain any known therapeutically useful constituent.

Counts 3 and 4. These counts (R. 5-8) involve a shipment of a vitamin product called "Pluri-B," the labels of which represented that each cubic centimeter contained 50 milligrams of thiamine hydrochloride (R. 35). It was stipulated (R. 15) that on or about August 30, 1945, a Food and Drug Inspector had secured a sample of this product from a doctor to whom petitioners had shipped it on or about July 16, 1945, and, after sealing it, had sent it by mail to the Vitamin Division, Food and Drug Administration, Washington, D. C. Dr. Chester D. Tolle, of the Food and Drug Administration in Washington, testified that when he received the sample, the vial appeared to be full and not to have been tampered with (R. 212). He further testified that it is the practice of the Administration to have inspectors make notations on their reports if samples collected by them have been opened, and, in such event, he would not have had the sample analyzed in his laboratory (R. 213). Mr. Capps, a chemist in the Vitamin Division (R. 97), testified that on September 24, 1945 (R.

97), he examined this vial of Pluri-B and found that it contained only 33 milligrams of thiamine hydrochloride per cubic centimeter (R. 99-100). He further testified that in a properly made solution, thiamine hydrochloride is very stable except when exposed to extremely high temperatures (R. 100).

Petitioner Bavouset testified that this product was made in a proper acid base and would substantially retain its potency for a year (R. 131, 149, 151) and that petitioners' products are bottled and sealed by the most improved methods, designed to prevent the entrance of impurities, to protect the contents from light, and to keep the contents in a reasonably good state of preservation (R. 131-132). Bavouset further admitted that at the time this drug was shipped, his laboratory did not have the equipment to make a thiachrome determination for thiamine (R. 144).

Count 7. This count involves a shipment of a sterile solution of Pluri-B, which was alleged to be adulterated by reason of the presence of undissolved matter. It was stipulated (R. 16-17) that the shipment to a doctor was made on or about June 18, 1946, and that on or about July 12, 1946, a Food and Drug Inspector collected a sample, consisting of six vials, from the doctor, and, after sealing it, sent it to the Pharmacology Division, Food and Drug Administration, Washington, D. C., via railway express. Dr. Frank H. Wiley,

Chief of the Chemical Section, Medical Division, Food and Drug Administration (R. 32), testified that he received the sample, with all the vials sealed, capped and full (R. 226), on July 23, 1946, and examined it on August 1, 1946 (R. 33, 38), when he found a considerable quantity of undissolved material visible to the naked eye (R. 34). On June 17, 1947, the date of his testimony, the amount of undissolved material was the same as when he first examined it (R. 37-38). In his opinion, the undissolved material was present on June 18, 1946, the date of the shipment by petitioners (R. 42). Only such an improbable factor as transmitting the sample to Washington in a refrigerator car might have hastened the crystallization if it had not taken place earlier (R. 42). Dr. Wiley testified that the presence of the noted undissolved materials was the result of a supersaturated solution of riboflavin (R. 44) and that the sample contained about twenty times as much riboflavin as may ordinarily be dissolved in a water solution (R. 46). Riboflavin is stable and will remain dissolved if the amount is below the saturation point (R. 44). Although petitioner Bavouset and Dr. Icke, a witness for petitioners, testified that the undissolved material should dissolve if the vial were put in water of about 110°-120° Fahrenheit (R. 145, 190), Dr. Wiley testified that he had placed the vials in warm water of about 150° for ten to fifteen minutes, and that the undis-

solved material remained (R. 226-227). Dr. Clinton H. Thienes testified concerning the dangers inherent in the presence of undissolved material in a sterile solution intended, as this was, for intravenous or intramuscular injection (R. 49-51).

ARGUMENT

Simply stated, petitioners' argument comes down to the contention that the Government was obliged to prove by affirmative evidence that the samples involved were not subjected to extraordinary, highly improbable handling between the time of shipment by petitioners and the time they were analyzed by the Food and Drug experts, although there was not the slightest suggestion of any facts indicating that the products were handled other than in the usual course of business.

Petitioners' argument, if accepted, would require the Government to follow the products through the mails or railway express, tracing them throught the hands of each and every one of the numerous mail clerks, etc., who, undoubtedly unknowingly, may have handled the much larger packages or mail bags in which these samples were anonymously contained. Then too, evidence would be required not only that the doctors who received the drugs did not perform the most unusual operations which might have caused the inadequate conditions which examination of the drugs disclosed, but also that those who may have assisted the doctors, did not irrationally and for

no conceivable reason subject the products to such extraordinary treatment.

As to the Indoform, the evidence was that it would remain stable unless boiled at 212° Fahrenheit for from five to six hours. Petitioner apparently contends that the Government was required to adduce the specific negative testimony of each of the numerous people who might at some time have come in contact with the samples that he did not boil the samples for five or six hours. Further, however, it should be noted that as to counts 1 and 2, petitioner Bavouset admitted that at the time of shipment the Indoform did not contain any of the only active, therapeutically valuable component of thyroid, nor the advertised amount of posterior pituitary. Thus, even acceptance of petitioners' contention would not require reversal of the convictions on counts 1 and 2.

The negative fact which petitioners would require the Government to establish as to the Pluri-B involved in counts 3 and 4 is that none of the innumerable persons who at any time handled the samples subjected them to extremely high temperatures, considerably in excess of those which might be reached in ordinary weather conditions. And this would be required despite petitioners' admission that their laboratory at the time of this shipment did not have the equipment required to make the accepted test for thiamine hydrochloride potency.

And as to the sterile Solution of Pluri-B forming the basis of count 7, petitioners would require the Goverment to prove by affirmative evidence that the samples were not sent by refrigerator car and that other ingredients had not been added to them, although the evidence showed that they were sealed, capped and full upon receipt by the government analysts.

As the court below fully pointed out (R. 244-247), the burden on the Government in a criminal case is to prove all the essential elements of an offense beyond a reasonable doubt; there is no requirement that the Government prove its case beyond any possible doubt which might be raised by sheer speculation and conjecture by ingenious counsel. See *Henderson* v. *United States,* 143 F. 2d 681, 682 (C.C.A. 9); *Rose* v. *United States,* 149 F. 2d 755, 759 (C.C.A. 9); *United States* v. *S. B. Penick & Co.,* 136 F. 2d 413, 415 (C.C.A. 2); and other authorities cited by the court below (R. 244-247). See also, *Bishop* v. *United States,* 107 F. 2d 297, 303 (App. D.C.); *United States* v. *Guthrie,* 171 Fed. 528, 532 (S.D. Ohio); *United States* v. *Dexter,* 154 Fed. 890, 894 (N.D. Iowa); *United States* v. *Reid,* 210 Fed. 486, 490 (D. Del.); *United States* v. *Wilson,* 176 Fed. 806, 809-810 (C.C.S.D. Fla.).

The court below relied upon the wholly unrebutted presumption of regularity in the conduct of normal business affairs on the part of government officers and private individuals. The Food

and Drug employees who made the analyses and examinations of the samples all testified that they handled the products in the normal, ordinary manner. When the vials were first received for analysis, they all were full and appeared not to have been opened (R. 79-80, 215, 212, 213, 226). In the absence of any evidence that they had been tampered with or handled in any manner other than according to the usual course of handling of such commodities, the court reasonably applied the common sense, long-established legal presumption of regularity in the conduct of the government officers and employees and of the private individuals who may have handled the materials. Cf. *United States Bank* v. *Dandridge,* 12 Wheat 64, 69-70; *United States* v. *Chemical Foundation,* 272 U.S. 1, 14-15; *Boerner* v. *United States,* 30 F. Supp. 635, 637 (E. D. N. Y.), affirmed, 117 F. 2d 387 (C.C.A. 2), certiorari denied, 313 U.S. 587; *International Shoe Company* v. *Federal Trade Commission,* 280 U.S. 291, 302; and other cases cited by the court of appeals (R. 247-250).

Appended to petitioners' brief in support of their petition for a writ of certiorari is a copy of an unreported opinion of the District Court for the Southern District of California in *United States* v. *Boyle,* which petitioners argue is in conflict with the decision in the instant case. In the first place, it should be noted that even if the claimed inconsistency were present, it would not

call for review by this Court since to the extent that there might be any conflict, the opinion of the Ninth Circuit here attacked would be controlling.

At any rate, in the instant case the evidence is clear that none of the commodities involved would be adversely affected by conditions normally to be expected in the course of routine transportation and handling. That the government inspectors shipped the samples to the analysts by mail is consistent with the absence of any handling instructions on the label and with petitioners' own use of the mails for shipment (R. 121). The opinion in the *Boyle* case does not disclose that any such evidence was presented as to the commodities there involved.

Finally, petitioners argue that the criminal provisions of the statute should be strictly construed. It is not clear, however, in what respect it is claimed that the statute was not strictly construed. The Act makes it an offense to introduce adulterated or misbranded commodities into interstate commerce. The interstate shipments here were admitted. The facts that the samples were adulterated and were not as represented on the label when analyzed by the government chemists, were undisputed. The trial judge found, as a matter of fact, that the drugs were adulterated and misbranded when shipped by petitioners. Even if the judge's findings of fact were erroneous as not supported by evidence, that circumstance would not demonstrate

that the criminal provisions of the statute had not been strictly construed. There is no claimed ambiguity in the statute, nor is there any question of interpretation of the Act involved. The trial court, sustained by the circuit court of appeals, found facts constituting a violation of the strict, unambiguous terms of the Act. We submit, therefore, that petitioners' contention that the Act should be strictly construed is irrelevant to the situation here presented, which involves simply a matter of evidence.

CONCLUSION

The decision below is correct and no real conflict is involved. We respectfully submit, therefore, that the petition for a writ of certiorari should be denied.

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OCTOBER 1948.

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